point out and distinctly claim the subject matter which the applicant regards as the invention.

The Examiner has rejected claims 11-16 and 38-39 under 35 U.S.C. §112, first paragraph, asserting that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Examiner has rejected claims 10-16, 25, 30, 35 and 38-39 under 35 U.S.C. §112, first paragraph, asserting that the specification does not reasonably provide enablement commensurate with the scope of the claims.

The Examiner has rejected claim 11-13 under 35 U.S.C. §102(b) asserting that the claims are clearly anticipated by p. 167 of the 1994-1995 Promega catalog.

The Examiner has rejected claim 10, under 35 U.S.C. §103(a) as being unpatentable over p. 167 of the 1994-1995 Promega catalog.

The Examiner has rejected claims 11-16, 25, 30 and 39 under 35 U.S.C. §102(e) asserting that the claims are anticipated by U.S. Patent No. 5,733,748 (filed June 6, 1995).

The Examiner has rejected claims 10 and 35, under 35 U.S.C. §103(a) asserting that the claims are unpatentable over U.S. Patent No. 5,733,748 (filed June 6, 1995).

These rejections are believed to be overcome in part by the amendments and are otherwise traversed for reasons discussed below.

Overview of the Amendments

Basis for the amendments to claims can be found throughout the specification.

Claims 10, 11, 15, 30, and 38 have been amended to include the language fragments comprising at least about 10 nucleotides. Basis for this amendment can be found throughout the specification, for example, at the following location: page14, lines 1-6.

Claims 10, 11, 15, 30 have been amended to recite having at least about 70% identity. Basis for this amendment can be found throughout the specification, for example, at the following location: page 15, lines 14-25.

Claims 10, 11, 15, 30 have been amended to recite selectively hybridizing to. Basis for this amendment can be found throughout the specification, for example, at the following locations: originally presented claim 11; pages 26-31; and Examples 4-9, pages 61-68.

Claim 25 has been amended to include the language "fragments comprising at least about 8 amino acids." Basis for this amendment can be found throughout the specification, for example, at the following location: page 16, lines 20-23.

Claims 38 and 39 have been amended to include the language purified polynucleotide. Basis for this amendment can be found throughout the specification, for example, at the following locations: originally presented claim 11; and page

Accordingly, no new matter has been added by way of this amendment and the entry thereof is respectfully requested.

Addressing the Examiner's Rejections

1. Rejection of Claims 38 and 39 under 35 U.S.C. §101

The Examiner has rejected claims 38 and 39 under 35 U.S.C. §101, asserting that the claims are directed to non-statutory matter.

The Examiner asserted that the "gene" as claimed, absent limitation to "an isolated" or "purified" product, has the same characteristics as a gene *in situ* in a human being and therefore does not constitute patentable subject matter.

The language objected to by the Examiner has been removed from the claims. The applicants submit that the claims are now directed to statutory subject matter. Accordingly, withdrawal of the rejection of claims 38 and 39 under 35 U.S.C. §101 is respectfully requested.

2. Rejection of Claims 10-16, 25, 30, 35 and 38-39 under 35 U.S.C. §112, Second Paragraph

The Examiner has rejected claims 10-16, 25, 30, 35 and 38-39 under 35 U.S.C. §112, second paragraph, asserting that the claims are indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. The Examiner has asserted the following specific deficiencies in the claims.

A. "Claim 10"

The Examiner has asserted that claim 10 is vague and indefinite in the recitation of "having."

The language objected to by the Examiner has been removed from the claim.

B. "CS141"

The Examiner has asserted that claims 10, 11, 14, 25, 30, 15, and 38 are vague and indefinite in the recitation of "CS141."

The term "CS141" is described extensively throughout the specification (see, for example, pages 4-10; and Example 1, pages 55-57). However, in order to facilitate prosecution applicants have removed this language from the claims.

C. "Derived From"

The Examiner asserts that recitation of "derived from" is vague and indefinite in claims 11 and 15.

The term "derived from" is defined in the specification (see, for example, page 13, lines 14-25). However, in order to facilitate prosecution applicants have removed this language from the claims.

D. "Hybridizing To"

The Examiner asserts that recitation of "hybridizing to" is vague and indefinite in claim 11.

The term selectively "hybridizing to" has an art recognized meaning to one of ordinary skill in the art. Examples of types of selective hybridization are described throughout the specification (see, for example, pages 26-31), as well as, specific examples of using the polynucleotide sequences of the present invention in methods involving selective hybridization (see, for example, pages Examples 4-9, pages 61-68).

Accordingly, the applicants submit that the language "hybridizing to" would be clear to one of ordinary skill in the art and that the rejection of claim 11 under 35 U.S.C. §112, second paragraph, should be withdrawn.

E. "Recombinant Means/Synthetic Means"

The Examiner asserted that claims 12 and 13 are vague and indefinite in the recitation of "recombinant techniques" and "synthetic techniques," respectively.

The Examiner has objected to the language produced by "recombinant techniques" and produced by "synthetic techniques" asserting that "it is unclear how the two different production methods modify the claimed polynucleotide." The applicants disagree with the Examiner's position. Polynucleotides produced by recombinant means can have, for example, modifications not generally present when produced by synthetic means (e.g., methylation or capping, see, for example, specification, page 15, lines 7-13). Also, polynucleotides produced by synthetic means can have modifications not generally present when the polynucleotide is created by recombinant means (e.g., cleavage replacement, or modification of a 3' hydroxyl group, e.g., see specification, page 31, lines 22, to page 32, line 4).

Accordingly, the applicants submit that in recitation of "recombinant techniques" and "synthetic techniques" it would be clear to one of ordinary skill in the art how the two different production methods modify the claimed polynucleotide, and that the rejection of claims 12 and 13 under 35 U.S.C. §112, second paragraph, should be withdrawn.

F. "Percent Identity"

The Examiner asserts that recitation of "% identity" in claims 10, 11, 15, 25, 38, and 39 is vague and indefinite.

The Examiner asserts that claims 10, 11, 15, 25, 38, and 39 are vague and indefinite in the language "% sequence identity." The applicants respectfully disagree with the Examiner's position. On page 12, lines 5-24, the applicants discuss the use of available programs for calculating identity or similarity between sequences. Applicants submit that use of default parameters in these programs is routine and well within the abilities of one having ordinary skill in the art.

Absolute specificity and precision are not required in the claims. Claims need only reasonably apprize a person having ordinary skill in the art as to their scope. *Hybritech Inc., v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, Fed. Cir. 1986. The second paragraph of 35 U.S.C. §112 merely requires that an applicant set out and circumscribe a particular subject area with a reasonable degree of precision such that the metes and bounds of the invention are set forth. *Ex parte Head*, 214 USPQ 551, PTO Bd. App. 1981.

In view of the above amendments, the teachings of the specification and the level of ordinary skill in the present art, the applicants submit that the boundaries of the pending claims are capable of being understood by one of ordinary skill in the art. Therefore, the rejection of the claims under 35 U.S.C. §112, second paragraph, should be withdrawn.

G. "Claims 14, 25, and 30"

The Examiner asserts that recitation of "at least one CS141 epitope" is vague and indefinite. The Examiner asserts that "it is unclear what structural feature characterizes an epitope."

"Epitope" has an art recognized meaning to one of ordinary skill in the art and, further, is defined throughout the specification (see, for example, page 17, line 30, to page 18, line 17).

In view of the above amendments, the teachings of the specification and the level of ordinary skill in the present art, the Applicants submit that the boundaries of the pending claims are capable of being understood by one of ordinary skill in the art. Therefore, the rejection of the claims under 35 U.S.C. §112, second paragraph, should be withdrawn.

H. "Claim 30"

The Examiner asserts that recitation of "and fragments and complements thereof" is vague and indefinite.

Applicants have amended the claim to clarify the Markush group.

The court has consistently stated that claim language must be read in light of prior art and teachings of the specification. The standard is that the "definiteness of the language must be analyzed...in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art." *In re Moore*, 439 F.2d 1232, 169 USPQ 236 (CCPA 1971). A claim which is clear to one ordinarily skilled in the art when read in light of the specification, does not fail for indefiniteness. *Slimfold Mfg. Co. v. Kinkead Indus., Inc.*, 932 F2d 1453, 1 USPQ2d 1536 (Fed. Cir 1986).

In view of the above amendments, the teachings of the specification and the level of ordinary skill in the present art, the applicants submit that the boundaries of the claims are capable of being understood by one of ordinary skill in the art. Therefore, the rejection of claims 10-16, 25, 30, 35 and 38-39 under 35 U.S.C. §112, second paragraph, should be withdrawn.

3. Rejection of Claims 11-16 and 38-39 under 35 U.S.C. §112, First Paragraph

The Examiner has rejected claims 11-16 and 38-39 under 35 U.S.C. §112, first paragraph, asserting that the claims contain subject matter which was not described in the

specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

All of the claims objected to by the Examiner contained the language "gene."

The Examiner has objected to use of the word "gene" in the claims. Applicants believe the word "gene" has an art accepted meaning and that based on the teachings of the present specification analysis of the genomic organization of the claimed sequences is within the ability of one having ordinary skill in the art. However, in order to facilitate prosecution the word "gene" has been deleted from the claims.

In view of the above arguments and amendments, the applicants submit that the pending claims reasonably convey the claimed invention to one of ordinary skill in the art. Accordingly, the rejection of the claims under 35 U.S.C 112, first paragraph, should be withdrawn.

4. Rejection of Claims 10-16, 25, 30, 35 and 38-39 under 35 U.S.C. §112, First Paragraph

The Examiner has rejected claims 10-16, 25, 30, 35 and 38-39 under 35 U.S.C. §112, first paragraph, asserting that the specification does not reasonably provide enablement commensurate with the scope of the claims. The Examiner has asserted the following specific deficiencies in the claims.

The Examiner has objected to use of the language "CS141" and "gene" in the claims. These words have been deleted from the claims, as discussed above. Further, the question of "epitope" has also been discussed above.

The Examiner cannot merely assert that the specification is not enabling. The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. A patent may be enabling even though some experimentation is necessary. *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217 (Fed. Cir. 1988).

A considerable amount of routine experimentation is permissible if the specification provides a reasonable amount of guidance, with respect to the direction in which experimentation should proceed, to enable the determination of how to practice a desired embodiment of the claimed invention. *Ex parte Forman*, 230 USPQ 546, 547 (PTO Bd. Pat. App. & Int'f 1986). *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). The present specification provides guidance concerning epitopes (see, for example, page 17, line 30, to page 18, line 17; and Example 14, pages 79-80).

The Examiner has presented no evidence to support the assertion that undue experimentation would be required to practice the present invention, as claimed.

In view of the above arguments and amendments, the applicants submit that the pending claims are enabled and that the rejection of the claims under 35 U.S.C 112, first paragraph, should be withdrawn.

5. Rejection of Claim 11-13 Under 35 U.S.C. §102(b)

The Examiner has rejected claim 11-13 under 35 U.S.C. §102(b) asserting that the claims are clearly anticipated by p. 167 of the 1994-1995 Promega catalog.

The Examiner asserts that the claims are anticipated by bulk nucleotides as described in the Promega catalog based on the presence of the word "fragments" in the claims. "Fragments" are described throughout the specification and are defined, for example, on page 14, lines 1-6. Applicants submit that bulk nucleotides do not anticipate "a contiguous sequence of approximately at least about 6 nucleotides, preferably at least about 8 nucleotides, more preferably at least about 10-12 nucleotides, and even more preferably at least about 15-20 nucleotides corresponding, i.e., identical or complementary to, a region of a specific nucleotide sequence." (Specification, page 14, lines 2-6). Further, the claims have been amended to include the limitation that the polynucleotide fragments are at least about 10 nucleotides in length.

Accordingly, in view of the above information and arguments, the reference of 1994-95 Promega catalog, p. 167, cannot be said to teach all the elements of the present

invention. Therefore, the rejection of the claims under 35 U.S.C. §102(b), over 1994-95 Promega catalog, p. 167, should be withdrawn.

6. Rejections of Claim 10 Under 35 U.S.C. §103

The Examiner has rejected claim 10, under 35 U.S.C. §103(a) as being unpatentable over p. 167 of the 1994-1995 Promega catalog. The Examiner asserts that the test kits of the present invention would be *prima facie* obvious in view of the above 102(b) rejection of the polynucleotide sequences. However, in view of the above discussed amendments to the claims and relative to the cited art, the applicants submit that claim 10 distinguishes over the art because the cited art does not teach a "polynucleotide capable of (i) selectively hybridizing to and (ii) having at least about 70% identity with a sequence selected from the group consisting of SEQUENCE ID NO 1; SEQUENCE ID NO 2; SEQUENCE ID NO 3; SEQUENCE ID NO 4; SEQUENCE ID NO 5; SEQUENCE ID NO 6; SEQUENCE ID NO 7; SEQUENCE ID NO 8; SEQUENCE ID NO 9; SEQUENCE ID NO 12; SEQUENCE ID NO 13; fragments comprising at least about 10 nucleotides of any of SEQUENCE ID NOs 1, 2, 3, 4, 5; and complements thereof."

Accordingly, in view of the above information and arguments, the rejection of the claim under 35 U.S.C. §103, over 1994-95 Promega catalog, p. 167, should be withdrawn.

7. Rejection of Claim 11-16, 25, 30 and 39 Under 35 U.S.C. §102(e)

The Examiner has rejected claims 11-16, 25, 30 and 39 Under 35 U.S.C. §102(e) asserting that the claims are anticipated by U.S. Patent No. 5,733,748 (filed June 6, 1995).

For prior art to anticipate under 35 U.S.C. 102 it has to meet every element of the claimed invention: such a determination is one of fact. *Hybritech Inc. v. Monoclonal Antibodies*, 802 F.2d at 1367, 231 USPQ 81 (Fed. Cir. 1986).

The accompanying figures (Appendix A and Appendix B) show rough alignments of the cited sequences relative to the claimed sequences of the present invention. The alignments were based on the "query" sequence beginning and end locations as recited in the MPSRCH alignments. The following can be seen from the comparisons in the figures:

(i) none of the prior art sequences anticipate any of the specific, complete claimed sequences (i.e., Appendix A -- intact SEQUENCE ID NO 1; SEQUENCE ID NO 2; SEQUENCE ID NO 3; SEQUENCE ID NO 4; SEQUENCE ID NO 5; SEQUENCE ID NO 6; SEQUENCE ID NO 7; SEQUENCE ID NO 8; SEQUENCE ID NO 9; SEQUENCE ID NO 12; SEQUENCE ID NO 13; Appendix B -- intact SEQUENCE ID NO 25; SEQUENCE ID NO 26; SEQUENCE ID NO 27; SEQUENCE ID NO 28);

(ii) fragments comprising at least about 10 nucleotides of any of SEQUENCE ID NOs 1, 2, 3, 4, and cannot be anticipated by the exact prior art sequences cited by the Examiner, i.e., no sequences, including fragments, derived from these claimed sequences can be made to match the '748 patent sequence cited by the Examiner.

In view of the above amendments and arguments, the cited reference sequences cannot be said to teach all the elements of the present invention. Accordingly, there is no support for the claims being anticipated by the cited prior art under 35 U.S.C. §102(e) and withdrawal of the rejection is respectfully requested.

8. Rejections of Claims Under 35 U.S.C. §103

The Examiner has rejected claims 10 and 35, under 35 U.S.C. §103(a) asserting that the claims are unpatentable over U.S. Patent No. 5,733,748 (filed June 6, 1995).

Claims 10 and 35 distinguish over the '748 patent for the same reasons discussed in Section 7 above.

Accordingly, in view of the above information and arguments, the rejection of the claims under 35 U.S.C. §103, over the '748 patent sequences, should be withdrawn.

CONCLUSION

Applicant respectfully submits that the claims comply with the requirements of 35 U.S.C. §112 and define an invention that is patentable over the art. Accordingly, a Notice of Allowance is believed in order and is respectfully requested.

If the Examiner notes any further matters which the Examiner believes may be expedited by a telephone interview, the Examiner is requested to contact the undersigned.

Please direct all further communications in this application to:

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Respectfully submitted,

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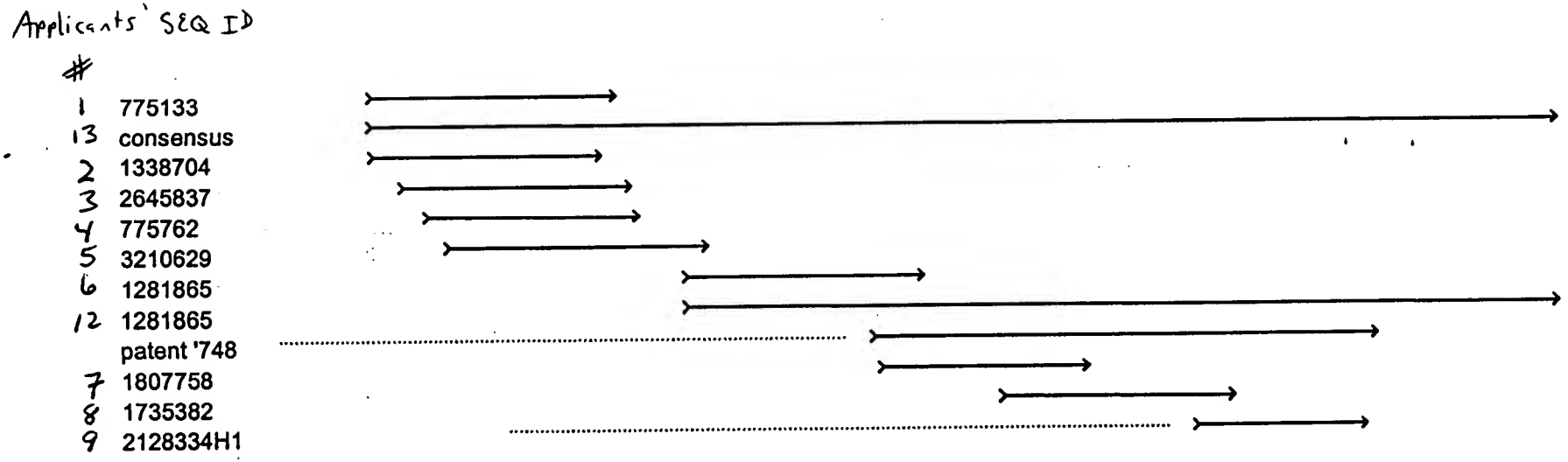
Applicants' SEQ ID
#
1 775133
13 consensus
2 1338704
3 2645837
4 775762
5 3210629
6 1281865
12 1281865
patent '748
7 1807758
8 1735382
9 2128334H1

Appendix A

- Underlined sequence is the sequence from US Patent 5,733,748
- **BOLD sequence** correspond to the Sequence ID No of the present invention (Sequence ID No is indicated over the bolded region).

Sequence ID NO 25

MRVSGVLRLLALIFAIVTTWMFIRSYMSFSMKTIRLP**RWLASPTKEIQVKKYKCGLIK**

Sequence ID NO 26

PCPANYFAFKICSGAANVVGPTMCFEDRMIMSPVKNNVGRGLNIALVNGTTGAV

Sequence ID NO 27

LGQKAFDMYSGDVMHLVKFLKEIPGGALVLVASYDDPGTKMNDESRKLFSDLGSSY

Sequence ID NO 28

AKQLGFRDSWVFIGAKDLRGKSPFEQFLKNSPDTNKYEGWPELLEMEGCMPPKPF

Synthetic Peptides

Sequence ID#25 **RWLASPTKEIQVKKYKCGLIKPCPANYFAFKICSGAAN**

Sequence ID#26 **GPTMCFEDRMIMSPVKNNVGRGLNIALVNGTTGAVLGQK**

Sequence ID#27 **KEIPGGALVLVASYDDPGTKMNDESRKLFSDLGSSYA**

Sequence ID#28 **WVFIGAKDLRGKSPFEQFLKNSPDTNKYEGWPELLEMEGC**

Appendix B